UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

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OPINION AND ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

Medisim Ltd. ("Medisim") brings this action against BestMed LLC ("BestMed") for patent and copyright infringement, unfair competition, false designation of origin, false advertising, deceptive acts and practices, unfair competition, and unjust enrichment. Currently before the Court are cross-motions, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[1] as well as Rules 702 and 403 of the Federal Rules of Evidence, to exclude expert testimony.[2] For the

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[1] 509 U.S. 579 (1993).

[2] *See* Medisim's Memorandum of Law in Support of Its Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("Medisim Mem."); BestMed's

reasons given below, the motions are granted in part and denied in part.

II. BACKGROUND

A. Procedural History

In November 2004, BestMed agreed to be the exclusive distributor for various Medisim products in the United States and Canada.[3] Medisim claims that BestMed began discussions with K-Jump Health Co., Ltd. ("K-Jump") to replace a patented Medisim thermometer while its agreement with Medisim was still in effect. As a result of those discussions, Medisim states that BestMed terminated its distribution contract with Medisim in 2009 and began selling a competing product manufactured by K-Jump.[4] BestMed denies these allegations,[5] and this lawsuit followed.

B. The Experts

Medisim seeks to disqualify Jack Goldberg, or, in the alternative to exclude parts of his reports.[6] BestMed seeks to exclude portions of Dr. David

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Memorandum of Law in Support of Its Motion to Strike Portions of Plaintiff's Experts, Lipson and Keegan ("BestMed Mem.").

[3] *See* Complaint ("Compl.") ¶ 9.

[4] *See id.* ¶¶ 11-13.

[5] *See* BestMed Answer, Affirmative Defenses, Counterclaims and Jury Demand ("Answer") ¶ 11.

[6] *See* Medisim Mem. at 1.

Lipson's report, as well as the entire report of Dr. Warren J. Keegan.[7] Each expert's background is described below**.**

1. Jack Goldberg[8]

Goldberg has two degrees in electrical engineering and computer science: a Bachelor's degree received in 1973 and a Master's degree received in 1978. From 1978 to 1984, he worked at various corporations involved in designing scientific equipment, with increasing levels of responsibility. In 1984, Goldberg began working at IVAC – an Eli Lilly subsidiary – on various projects, and served as technical director in the development of a new infrared thermometer. Eventually, he became the supervisor of IVAC's entire line of thermometers. Since leaving IVAC in 1995, Goldberg has served as President of Metronix, Inc. In that role, Goldberg has consulted on various medical equipment projects – including thermometers – as well as software design matters. He has also worked for several hearing aid companies.

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[7] *See* BestMed Mem. at 1.

[8] These facts are drawn from Goldberg's resume. *See* Expert Report of Jack Goldberg Regarding Invalidity and Unenforceability of U.S. Patent No. 7,597,668 and False Patent Marking in Relation to U.S. Patents No. 6,280,397 and 7,597,668 ("Goldberg Report"), Ex. A to Declaration of Richard H. Brown, Attorney for Medisim ("Brown Decl."), at 92-102.

2. Dr. David Lipson[9]

Lipson – the named inventor on nearly thirty U.S. patents – attended Cornell University, which awarded him a Bachelor's Degree in electrical engineering in 1973. He did his graduate work in biomedical engineering at Case Western Reserve University, where he earned a Master's Degree in 1975 and a Ph.D. in 1979. Over the course of his career, he has worked at various medical and pharmaceutical corporations, including Abbott Labs and IVAC, where his tenure briefly overlapped with Goldberg's. He has taught at Cornell University since 2004, and is a Senior Member of the Institute of Electrical and Electronics Engineers.

3. Dr. Warren Keegan[10]

Keegan studied economics at Kansas State University, where he obtained a Bachelor's Degree in 1958 and a Master's Degree the following year. By 1967, he earned two additional degrees – a Master's Degree and a Doctorate – from the Harvard Business School. Keegan has taught at the post-graduate level for the past thirty years at various prestigious institutions, including the Columbia Business School, the George Washington University, the Stern School of Business

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[9] These facts are drawn from Lipson's resumé. *See* Ex. A to Expert Report of David Lipson, Ph.D. ("Lipson Report"), Ex. 1 to BestMed Mem.

[10] These facts are drawn from Keegan's resumé. *See* Ex. 1 to Expert Report of Dr. Warren J. Keegan ("Keegan Report"), Ex. 10 to BestMed Mem.

at NYU, and Pace University, where he now serves as a full professor. He has published many professional and scholarly articles, and is also the author of a marketing management textbook. In the private sector, Keegan has worked as a consultant at various corporations and consultancies, including General Motors and the Boston Consulting Group. He also runs Keegan & Company LLC and Warren Keegan Associates, Inc., which engage in litigation consulting and management consulting, respectively.

C. The Expert Reports

1. Goldberg's Reports

BestMed retained Goldberg primarily to analyze the validity of various claims of U.S. Patent No. 7,597,668 ("the '668 Patent"). In his initial report, Goldberg concluded that the '668 Patent failed the enablement and written description requirements of Section 112 of Chapter 35 of the United States Code,[11] as well as the non-obviousness requirement of Section 103.[12] He also concluded that the '668 Patent was anticipated under Section 102.[13] Finally, Goldberg concluded that Medisim failed to disclose material information to the Patent and Trademark Office, and that it falsely marked several devices in violation of Section

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[11] *See infra* Part III.A.3.

[12] *See infra* Part III.A.4.

[13] *See id.*

292 of Chapter 35 of the United States Code.[14]

In his rebuttal report, Goldberg was asked to respond to the expert report of Andrew Carter, as well as Lipson's report, on the issues of alleged infringement of the '668 Patent and the availability of acceptable non-infringing substitutes.[15] He concluded that the accused BestMed products did not in fact infringe the '668 Patent, and that there were "numerous acceptable non-infringing substitutes for the Patented Technology."[16]

C. The Lipson Report

Medisim retained Lipson "to analyze digital temple thermometers marketed and/or sold by BestMed . . . and to opine on whether such products infringe any claim of . . . the '668 Patent."[17] He concluded that BestMed directly infringed eight claims of the '668 Patent, and induced or contributed to the

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[14] *See* Goldberg Report at 16-20.

[15] *See* Rebuttal Expert Report of Jack Goldberg Regarding the Alleged Infringement of U.S. Patent No. 7,597,668 by BestMed's Products and the Availability of Acceptable Noninfringing Substitutes for the Patented Technology ("Goldberg Rebuttal Report"), Ex. B to Brown Decl., at 4.

[16] *Id.* at 13.

[17] Lipson Report at 2.

infringement of six more.[18] Lipson also wrote a rebuttal to the Goldberg Report.[19]

D. The Keegan Report

Keegan conducted a consumer survey "to determine whether there is a likelihood of confusion among consumers between the plaintiff Medisim's digital temple thermometer and the defendant BestMed's digital temple thermometer."[20] Using an Internet-based survey platform, respondents were randomly assigned to either a test cell or a control cell.[21] Each respondent was shown a picture of a product and directed to "take as much time to look at [it] as you would if you were considering purchasing it."[22] The respondent was then shown another photograph of a different product,[23] and asked two questions. *First*, he was asked if he thought the two products were manufactured by the same company, or by different

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[18] *See id.* at 4-5.

[19] *See* Rebuttal Expert Report of David Lipson, Ph.D., Ex. 3 to Medisim Mem., at 2.

[20] Keegan Report at 1.

[21] *See id.* at 4.

[22] Survey Questionnaire, Ex. 5 to Lipson Report.

[23] Test-cell respondents were shown pictures of a Medisim thermometer and a BestMed thermometer, both in RiteAid branded packaging, while control-cell respondents were shown pictures of a Medisim thermometer and a third-party thermometer. While both thermometers in the control cell were RiteAid branded, the third-party thermometer had to be digitally altered to that effect. *See* Keegan Report at 3.

companies. *Second*, he was asked if he though the two products were manufactured by companies that were affiliated, connected, or associated with one another.[24] Respondents who answered positively to either question were coded as indicating a likelihood of confusion.[25] Using this protocol, Keegan found that eighty-three percent of test cell respondents and fifty-two percent of control cell respondents showed a likelihood of confusion, for a net confusion level of thirty-one percent.[26] On this basis, he concluded that "the difference between the test and control cell results is statistically significant at the 95 percent confidence level [and that] these survey results confirm the presence of a likelihood of confusion in this case."[27]

III. APPLICABLE LAW

A. Admissibility of Expert Testimony Generally

The proponent of expert evidence bears the initial burden of

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[24] *See id.* at 6.

[25] Keegan also used screening questions to ensure that survey respondents(1) were at least eighteen years old, (2) had shopped or were likely to shop at RiteAid, CVS, Walmart, or Walgreens within three months of the survey date, (3) had used an electronic thermometer on themselves or a family member within the past twelve months. *See id.* at 5.

[26] *See id.* at 6.

[27] *Id.* at 6-7.

establishing admissibility by a "preponderance of proof."[28] Federal Rule of Evidence 702 states the requirements for the admission of expert testimony as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Under Rule 702 and *Daubert*, the district court must determine whether the proposed expert testimony "both rests on a reliable foundation and is relevant to the task at hand."[29] That is, the district court must act as "'a gatekeeper to exclude invalid and unreliable expert testimony.'"[30] Nonetheless, "the Federal Rules of

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[28] *Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987) (discussing Rule 104(a) of the Federal Rules of Evidence). *Accord Daubert*, 509 U.S. at 592 & n.10 (citing *Bourjaily*, 483 U.S. at 175-76, and explaining that the proponent of expert testimony must prove admissibility by a preponderance of proof).

[29] 509 U.S. at 597. *Accord Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-49 (1999).

[30] *Bickerstaff v. Vassar Coll.*, 196 F.3d 435, 449 (2d Cir. 1999) (quoting *Hollander v. American Cyanamid Co.*, 172 F.3d 192, 202 (2d Cir. 1999)). *Accord Louis Vuitton Malletier v. Dooney & Bourke, Inc.* ("*Vuitton IV*"), 525 F. Supp. 2d 558, 561-65 (S.D.N.Y. 2007) (discussing district court's "special obligation" to gatekeep with respect to expert evidence).

Additionally, expert testimony may not usurp the role of the court in determining the applicable law. *See United States v. Lumpkin*, 192 F.3d 280, 289

Evidence favor the admissibility of expert testimony, and [the court's] role as gatekeeper is not intended to serve as a replacement for the adversary system."[31] Accordingly, in serving as gatekeeper, the court must focus on the principles and methodologies underlying the expert's conclusions, rather than on the conclusions themselves.[32] To this end, courts may consider (1) "whether [the method or theory] can be (and has been) tested," (2) "whether [it] has been subjected to peer review and publication," (3) "the known or potential rate of error [associated with the technique] and the existence and maintenance of standards controlling the technique's operation," and (4) whether the method has achieved "general acceptance" within the relevant community.[33]

The court's objective when exercising this gatekeeping function is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual

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(2d Cir. 1999). Although an expert "may opine on an issue of fact," an expert "may not give testimony stating ultimate legal conclusions based on those facts." *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991). Expert testimony is also inadmissible when it addresses "lay matters which [the trier of fact] is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

[31] *Vuitton IV*, 525 F. Supp. 2d at 562 (citation and quotation marks omitted).

[32] *See Daubert*, 509 U.S. at 595.

[33] *Id.* at 592-95.

rigor that characterizes the practice of an expert in the relevant field."[34] However, recognizing that "there are many different kinds of experts, and many different kinds of expertise," the Supreme Court has emphasized that the reliability inquiry "is a flexible one."[35] Accordingly, the factors "identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[36] Ultimately, the inquiry "depends upon the particular circumstances of the particular case at issue."[37] In sum, the trial court has "the same kind of latitude in deciding *how* to test an expert's reliability . . . as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable."[38]

In addition to the forgoing, Federal Rule of Evidence 403 states that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Because "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it[,] the judge in weighing

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34 *Kumho Tire Co.*, 526 U.S. at 152.

35 *Id.* at 150.

36 *Id.* (quotations omitted).

37 *Id.*

38 *Id.* at 152 (emphasis in original).

possible prejudice against probative force under Rule 403 . . . exercises more control over experts than over lay witnesses."[39]

B. Admissibility of Survey Evidence

Consumer surveys are often used to demonstrate or refute a likelihood of consumer confusion in cases brought under the Lanham Act.[40] Obviously, "[s]urveys do not measure the degree of actual confusion by real consumers making mistaken purchases. Rather surveys create an experimental environment from which we can get useful data from which to make informed inferences about the likelihood that actual confusion will take place."[41]

Reliance on surveys is not without hazards. Indeed, "any survey is of necessity an imperfect mirror of actual customer behavior under real life conditions . . . . It is notoriously easy for one survey expert to appear to tear apart the

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[39] *Id.* (quotation marks omitted).

[40] *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 225-28 (2d Cir. 1999).

[41] 6 McCarthy on Trademarks § 32:184 at 32-392. As McCarthy explains, "[d]irect evidence of actual confusion can come only from such sources as misdirected phone calls or letters or even from that rarest of evidence, the testimony of someone willing to testify that they were once a confused customer." *Id.* Although survey evidence is not direct evidence of actual confusion, it is nonetheless routinely categorized "under the heading of 'actual confusion.'" *Id.* at 32-393.

methodology of . . . another."[42] Practically speaking, there is "no such thing as a 'perfect' survey. The nature of the beast is that it is a sample, albeit a scientifically constructed one."[43]

To assess the validity and reliability of a survey, a court should consider a number of criteria, including whether:

> (1) the proper universe was examined and the representative sample was drawn from that universe; (2) the survey's methodology and execution were in accordance with generally accepted standards of objective procedure and statistics in the field of such surveys; (3) the questions were leading or suggestive; (4) the data gathered were accurately reported; and (5) persons conducting the survey were recognized experts.[44]

"[T]he closer the survey methods mirror the situation in which the ordinary person would encounter the trademark, the greater the evidentiary weight of the survey results."[45] The failure of a survey to approximate actual marketplace conditions

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[42] *Id.* § 32:178 at 32-380.

[43] *Id.* at 32-380 to 32-381.

[44] *Louis Vuitton Malletier\ v. Dooney & Bourke, Inc.* ("*Vuitton I*"), 340 F. Supp. 2d 415, 433 (S.D.N.Y. 2004) (citation and alterations omitted), *vacated on other grounds by Vuitton II*, 454 F.3d at 117. *See also* Manual for Complex Litigation § 11.493 at 103 (Federal Judicial Center 4th ed. 2004) (setting out seven criteria); Shari Seidman Diamond, Reference Guide on Survey Research, *in* Reference Manual on Scientific Evidence ("Diamond on Survey Research") at 359, 373-418 (Federal Judicial Center 3d ed. 2011) (discussing criteria to be considered to determine the admissibility of and weight to be accorded to survey evidence).

[45] 6 McCarthy on Trademarks § 32:163 at 32-333.

can provide grounds for inadmissibility.[46] Finally, while errors in survey methodology usually go to weight of the evidence, a survey should be excluded under Rule 702 when it is invalid or unreliable, and/or under Rule 403 when it is likely to be insufficiently probative, unfairly prejudicial, misleading, confusing, or a waste of time.[47]

C. The Enablement Requirement of Patent Law

The so-called "enablement" requirement of patent law is set forth in Section 112 of Chapter 15 of the United States Code, which reads as follows:

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[46] *See Troublé v. Wet Seal*, 179 F. Supp. 2d 291, 308 (S.D.N.Y. 2001) ("Although no survey can construct a perfect replica of 'real world' buying patterns, a survey must use a stimulus that, at a minimum, tests for confusion by roughly simulating marketplace conditions."); *see also American Footwear Corp. v. General Footwear Co. Ltd.*, 609 F.2d 655, 660 n.4 (2d Cir. 1979) (holding district court decision to exclude survey "for failure to conduct it under actual marketing conditions" not clearly erroneous). *But cf. Vista Food Exch., Inc. v. Vistar Corp.*, No. 03-CV-5203, 2005 WL 2371958 at *5-7 (E.D.N.Y. Sept. 27, 2005) (noting that failure to approximate actual marketplace conditions is only one factor amongst many to consider when determining what weight, if any, to give to a survey).

[47] *See Schering*, 189 F.3d at 228; *Starter Corp. v. Converse, Inc.*, 170 F.3d 286, 296-98 (2d Cir. 1999) (affirming district court's exclusion of survey where any probative value was outweighed by prejudicial effect); *Vuitton IV*, 525 F. Supp. 2d at 568 (adopting Special Masters' recommendation to exclude flawed survey under Rules 702 and 403); 6 McCarthy on Trademarks § 32:170 at 32-351 to 32-352 ("In an extreme case, an improperly conducted survey with slanted questions or serious methodological defects may be excludable as 'irrelevant' of the true state of mind of potential purchasers. . . . [However, t]he majority rule is that while technical deficiencies can reduce a survey's weight, they will not prevent the survey from being admitted into evidence.").

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

"To be enabling, a patent's specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."[48] While courts frequently state that a patent's specification need not disclose what is well-known in the art, the Federal Circuit has firmly established that this "is merely a rule of supplementation, not a substitute for a basic enabling disclosure."[49]

In determining if a patent specification is enabling – that is, if it does not require undue experimentation – courts must balance the so-called *Wands* factors, which include

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability

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[48] *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citations and quotations omitted).

[49] *Id.*

of the art, and (8) the breadth of the claims.[50]

The Federal Circuit has made clear that these factors are "illustrative, not mandatory."[51] Accordingly, a court need analyze only those *Wands* factors that the facts indicate are relevant.[52]

IV. DISCUSSION

A. Medisim's Motion

1. Goldberg Is Qualified as an Expert

Medisim argues that Goldberg is not qualified as "an expert in the area of digital, conductive thermometry" because he has not worked in the medical device field since leaving IVAC in 1995. It also argues that his experience there was only tangentially related to thermometry, and that he has been "principally a professional expert witness" since then.[53] Accordingly, Medisim asserts that Goldberg's "experience is stale and outdated," and urges this court to exclude his report and prevent him from testifying at trial.[54]

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[50] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

[51] *Streck, Inc.*, 665 F.3d at 1289 (citing *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

[52] *See Amgen, Inc.*, 927 F.2d at 1213.

[53] *See* Medisim Mem. at 1, 7.

[54] *Id.*

Medisim's characterization of Goldberg's tenure at IVAC as tangential to thermometry is misleading for several reasons. *First*, Goldberg led the team that developed IVAC's first infrared digital thermometer. *Second*, he managed IVAC's entire team of thermometry-focused engineers. *Finally*, as a result of his work at IVAC, he was awarded a patent for an infrared thermometer.[55] In sum, Goldberg was deeply involved with thermometry while at IVAC, in a manner more than sufficient to pass muster under Rule 702 and *Daubert*.

Medisim next argues that even if Goldberg *was* an expert, he no longer is today because he "has done no non-litigation expert work involving thermometry for over 15 years."[56] Once again, this argument mischaracterizes the facts. Since leaving IVAC, Goldberg continued to work with medical device manufacturers in a variety of fields and has consulted on several projects directly related to digital conductive thermometry.[57] Furthermore, he did an in-depth review of the general field of thermometry as part of a litigation project that lasted

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[55] *See* BestMed's Memorandum of Law in Opposition to Medisim's Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("BestMed Opp. Mem.") at 2-3.

[56] *See* Medisim Mem. at 7.

[57] *See* BestMed Opp. Mem. at 3-4.

from 2002 to 2005.[58] Accordingly, I find that Goldberg's expert qualifications are sufficiently up-to-date, and will not strike his reports for lack of expertise.

2. Goldberg May Rely on the Gilliand Report

Medisim asserts that "Goldberg's references to or testimony about the Gilliand Report [analyzing the source code of the FHT-1]" should be stricken for three reasons:[59] (1) that the Gilliand Report – which was prepared explicitly for this litigation – is not something "that would reasonably be relied upon by experts in the field,"[60] (2) that Goldberg simply parrots Gilliand without applying his own expertise to Gilliand's findings,[61] and (3) that Goldberg's references to the Gilliand

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[58] Medisim argues that much of Goldberg's relevant experience should not be considered because it was not timely disclosed in accordance with this Court's Scheduling Order of May 18, 2010. *See* Medisim Reply Memorandum of Law in Support of Its Motion to Disqualify Defendant's Proposed Expert, Jack Goldberg, or, in the Alternative, to Strike Portions of Goldberg's Reports ("Medisim Rep. Mem.") at 1 (citing Federal Rule of Civil Procedure 26(a)(2)(D)). Under Rule 26(e), however, a party has an ongoing duty to supplement an expert report "in a timely manner if the party learns that in some material respect the disclosure . . . is incomplete . . . ." Prior to the filing of these motions, BestMed could not have known how Medisim would challenge Goldberg's expert qualifications. Now that is has those challenges, BestMed has taken the earliest possible opportunity to respond. Accordingly, BestMed's supplementation is timely, and may be considered on these motions.

[59] Medisim Mem. at 8.

[60] *Id.*

[61] *See id.* at 9-11.

Report amount to improper bolstering.[62]

The suggestion that materials prepared for purposes of litigation do not qualify as facts or data "of a type reasonably relied upon by experts in the field" is unduly restrictive. As the Fifth Circuit has explained, the fact that the report of a consulting expert was prepared "in anticipation of litigation does not mean that it cannot be the type of study an expert would rely upon in expressing his opinion."[63] Instead, a testifying expert may rely on such a report as long as it has sufficient indicia of reliability.[64] Because there is no indication that the Gilliand Report is unreliable, Medisim's first basis to strike references to Gilliand fails.

Where a testifying expert has expertise in the field covered by a consulting expert and independently verifies the latter's conclusions, there is no danger that the former is acting as a mere "mouthpiece or conduit" of the latter.[65] Goldberg is qualified to analyze source code; in fact, he reviewed the same source

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62 *See id.* at 11.

63 *U.S. v. Marine Shale Processors*, 81 F.3d 1361, 1370 (5th Cir. 1996).

64 *See id.*

65 Medisim Mem. at 10.

code documents as Gilliand.[66] Furthermore, the context in which Goldberg refers to the Gilliand Report makes clear that he does so only after analyzing the source code on his own. That he reached the same conclusions as Gilliand does not mean that he "parrots Gilliand's opinion without adding any analysis."[67] Accordingly, Medisim's second basis to strike references to the Gilliand Report also fails.

At bottom, Medisim's effort to strike references to the Gilliand Report rests largely on the misplaced concern that such references amount to improper bolstering. As the Fourth Circuit has explained, referring to the conclusions of a non-testifying expert is improper if done in an attempt to trade on the non-testifying expert's superior professional reputation.[68] Nothing here indicates that Goldberg attempted to take advantage of Gilliand's professional reputation, or that his reputation was superior to Goldberg's in the first place. For this and all the other reasons given above, Goldberg's references to the Gilliand Report will not be stricken.[69]

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[66] *See* Goldberg Report at 107 (listing source code documents considered).

[67] Medisim Mem. at 10.

[68] *See U.S. v. Tran Trong Cuong*, 18 F.3d 1132, 1144 (4th Cir. 1994).

[69] Medisim also argues that disclosing Gilliand's conclusions to the jury would be improper under Federal Rule of Evidence 703, even if the opinions that Goldberg formed based on those conclusions are admissible. *See* Medisim Rep.

3. Goldberg May Provide His Enablement Opinions

Medisim puts forth two reasons to strike Goldberg's enablement opinions. *First*, it complains that Goldberg failed to evaluate the relevant prior art. *Second*, it argues that his conclusion regarding undue experimentation is an unsupported, *ipse dixit* opinion.[70]

a. Goldberg Considered the Relevant Prior Art

Medisim charges Goldberg with failing to consider the Seifert Patent and the Weiss Patent.[71] Lipson, Medisim's expert, argues that a person of ordinary skill in the art would have found these patents, and that they would have led such a person to other materials that would allow him to develop a predictive algorithm for use in a single-sensor conductive thermometer. In other words, these two prior art references would allow a person reasonably skilled in the art to fully implement the '668 Patent.[72]

As noted above, the law of enablement requires that the patent

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Mem. at 3. As there is no indication in the briefs that BestMed intends to introduce the Gilliand Report to explain Goldberg's opinions, the admissibility of the Gilliand Report for that purpose is reserved for trial.

[70] *See* Medisim Mem. at 12-14; *see also* Medisim Rep. Mem. at 5.

[71] *See* Medisim Mem. at 12.

[72] *See* Expert Rebuttal Report of David Lipson, Ph.D. ("Lipson Rebuttal Report"), Ex. 3 to BestMed Mem., at 18.

specification teach a person reasonably skilled in the art how to make and use the claimed invention without resorting to undue experimentation. However, the specification need not explicitly lay out minor details already well-known in the art. BestMed believes that it is improper to refer to the prior art to enable a predictive algorithm for use with single-sensor thermometer because such an algorithm is not a "minor detail," but rather a key feature of the invention claimed in the '668 Patent.[73] Medisim states that BestMed's belief should be rejected as "unsupported attorney argument."[74]

Goldberg expressly states that he considered all of the references listed in Exhibit C of his report, which includes both the Seifert Patent and the Weiss Patent.[75] Because he considered those references and *still* found that the '668 Patent specification did not enable a "one-sensor solution," it is reasonable to infer from his opinions that such a solution is not a "minor detail" that can be taught by referring to prior art, but rather should be described in the specification. While Goldberg did not expressly draw this conclusion, BestMed's argument is far from "unsupported." Accordingly, I find that Goldberg considered the relevant

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[73] *See* BestMed Opp. Mem. at 11.

[74] Medisim Rep. Mem. at 4 (internal quotations omitted).

[75] *See* Goldberg Report at 10.

prior art, and that BestMed's legal arguments on enablement do not exceed the opinions expressed in Goldberg's report.

b. Goldberg's Undue Experimentation Opinions Are Not Mere *Ipse Dixit* Conclusions

Continuing on with its litany of complaints about Goldberg's report, Medisim next argues that Goldberg relied solely on the "quantity of experimentation" factor in forming his opinion that the '668 Patent would require undue experimentation.[76] According to Medisim, "the vast majority of the work [Goldberg] describes is indisputably routine clinical work. . . ."[77] Furthermore, it states that Goldberg's opinion that developing a predictive algorithm for use with a single-sensor thermometer would be difficult is an "*ipse dixit* assertion" and "an unsupported net opinion."[78]

Goldberg's opinion that *deriving* a predictive algorithm for use with a single-sensor thermometer would be difficult is primarily based on the quantity of experimentation that would go into the effort.[79] However, Goldberg's opinion that the task of *validating* that algorithm "would have involved a great amount of

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76 *See* Medisim Mem. at 13.

77 *Id*.

78 *Id.* at 14.

79 *See* Goldberg Report at 28.

scientific and statistical effort" clearly goes beyond the mere quantity of experimentation and into the other *Wands* factors.[80]

This Court has discretion "to determine whether [an] expert acted reasonably in making assumptions of fact upon which he would base his testimony."[81] Given his expertise in the field of thermometry and his familiarity with other predictive thermometers, I find that Goldberg's determination that validating a predictive algorithm for a single-sensor thermometer would have required "a great amount of scientific and statistical effort" is not a mere *ipse dixit* conclusion. While Medisim may attack Goldberg's opinions in this realm via "[v]igorous cross-examination [and] presentation of contrary evidence," the simple fact that it believes them to be wrong is not grounds to strike them.[82]

4. Goldberg's Anticipation Opinions Are Partially Excluded

a. Goldberg Failed to Apply this Court's Claim Construction When Analyzing the '452 Patent

Medisim argues that Goldberg failed to determine whether the '452 Patent used "core body temperature" to mean "temperature of blood in the

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80 *Id.*

81 *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 22 (2d Cir. 1996).

82 *Daubert*, 509 U.S. at 596.

pulmonary artery," as construed in the *Markman* Order.[83] Goldberg agreed with that construction, calling it the "gold standard" in the field.[84] However, he completely fails to discuss whether the '452 Patent follows that standard. This is problematic, as Goldberg himself admits that "core body temperature" is used inconsistently in the field.[85] Without comparing the use of the term in the two patents, Goldberg's opinion that the '452 Patent anticipates the "calculates a core body temperature" limitation of the '668 Patent lacks a reliable foundation and must be stricken.

b. Goldberg May Testify that the FHT-1 Calculates a Core Body Temperature

In reaching his conclusion that the FHT-1 calculates a core body temperature, Goldberg relies heavily on two pieces of pre-*Markman* evidence: the deposition of Moshe Yarden – inventor of the '668 Patent – and Medisim's answer to a request to admit. In both instances, Medisim made clear that it objected to inquiries related to disputed claim terms, and that it answered subject to that objection.[86] Although BestMed believes that Medisim was required to supplement

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83 *See* Medisim Mem. at 15-16.

84 Goldberg Report at 72 n.12.

85 *See* Goldberg Rebuttal Report at 7.

86 *See* Medisim Mem. at 16-17.

its responses in light of this Court's *Markman* Order, it never sought an order directing Medisim to comply with that request.[87] Furthermore, since July 2011,[88] Medisim has strongly disputed that the *Markman* Order triggered such a duty.[89] Accordingly, BestMed's assertion that Medisim "incredibly" makes this argument for the first time on this motion rings hollow.[90]

The fact that Goldberg relied on arguably outdated materials provided to him by BestMed does not mean that he used unreliable methods. Instead, it indicates that his ultimate conclusions may be incorrect. Such a concern, however, goes to the weight to be accorded an opinion, not to its admissibility. Medisim can fully address its concerns regarding this portion of Goldberg's report on cross-examination, but it will not be stricken on this motion.

c. Goldberg May Testify that the FHT-1 Calculates Deep Tissue Temperature

Goldberg's conclusion that the FHT-1 calculates deep tissue temperature is based primarily on Medisim's admission that the FHT-1 uses its

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[87] *See* BestMed Opp. Mem. at 15 (citing Federal Rule of Civil Procedure 26(e)).

[88] *See* 7/21/11 Letter from Richard Brown, Attorney for Medisim, to Talivadis Cepuritis, Attorney for BestMed, Ex. A to the Second Supplemental Declaration of Richard Brown, at 1-2.

[89] *See* Medisim Mem. at 17.

[90] BestMed Opp. Mem. at 15.

proprietary R.A.T.E. technology. Goldberg explains why he believes the use of R.A.T.E. technology necessarily means that the FHT-1 calculates deep tissue temperature, and supports his opinion with reference to Medisim's own documents and witness testimony.[91] Nonetheless, Medisim complains that Goldberg "has no principled basis to opine that the FHT-1 product calculated a deep tissue temperature,"[92] asserting that Goldberg misused deposition testimony.[93] While Goldberg does cite to Yarden's deposition testimony explaining how the Accused Product infringes the '668 Patent, it was not unreasonable for him to use that deposition testimony when considering the FHT-1. This is so because that testimony involved a discussion of how Medisim's R.A.T.E. technology worked.[94] Accordingly, Goldberg may testify that the FHT-1 calculates a deep tissue temperature.[95]

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91 *See* Goldberg Report at 39.

92 *See* Medisim Mem. at 18.

93 *See id.* at 18-19.

94 *See* Goldberg Report at 39-40.

95 Medisim also argues that Goldberg's opinion is internally inconsistent because it equates two different variables with deep tissue temperature. *See* Medisim Mem. at 19. This criticism is misplaced, as it is clear that Goldberg associated the first variable – Tavg – with deep tissue temperature in his analysis *of the '668 Patent*, and associated the second variable – Tavg-27 – with deep tissue temperature in his analysis *of the FHT-1 source code*. *See* Goldberg Report at 41-43.

5. Goldberg May Not Provide His Opinion on Inequitable Conduct

All individuals associated with the filing and prosecution of a patent are under a duty to disclose to the patent examiner all information material to the patentability of the claimed invention. This duty does not extend, however, to prior art already considered by or known to the patent examiner,[96] who is deemed to have considered a reference listed in a search report if she initials the search history containing the reference, or the actual reference itself in the search history.[97]

A party that brings a claim of inequitable conduct based on non–disclosure of prior art must come forward with "clear and convincing evidence . . . that the applicant *made a deliberate decision* to withhold a *known* material reference."[98] Because materiality is determined on a but-for basis, an

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Medisim also suggests that Goldberg's reliance on "physics" is unexplained and should be stricken. *See* Medisim Mem. at 18. An holistic view of Goldberg's report makes it clear that he refers to the heat conduction physics noted in the '398 Patent. *See* Goldberg Report at 12. While Medisim may challenge his understanding and application of those physics via cross-examination, the charge that Goldberg did not explain them is without merit.

[96] *See* 37 C.F.R. § 1.56.

[97] *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1235-36 (Fed. Cir. 2003).

[98] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (emphasis in original).

inequitable conduct claim will fail unless "the PTO would not have allowed a claim had it been aware of the undisclosed prior art."[99]

Goldberg opines that the '668 Patent is unenforceable due to inequitable conduct for two reasons. *First*, he states that "Medisim failed to disclose to the PTO that it sold and offered for sale its own FHT-1 product and that the FHT-1 was in public use prior to May 31, 2005." Because he opined that the FHT-1 would have been material to the prosecution of the '668 Patent, Goldberg concludes that "if the patent examiner had been apprised of the prior art FHT-1 product . . . he would not have allowed the asserted claims of the '668 Patent . . ."[100] *Second*, Goldberg opines that "the asserted claims of the 668 patent would not have been allowed" if the patent examiner had been aware of the '436 Patent or the '452 Patent.[101]

Neither of these purported reasons are supported by the facts. *First*, the FHT-1 was disclosed to the patent examiner via an Information Disclosure Statement that included a provisional patent application describing the FHT-1.[102]

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99 *Id.* at 1291.

100 Goldberg Report at 77-78.

101 *Id.* at 79.

102 *See* Excerpts from the '668 Patent File History, Ex. N to the Brown Decl., at 176.

Second, while the '452 Patent and the '436 Patent were not expressly disclosed to the patent examiner, both patents are listed on a search history initialed by the examiner.[103] Accordingly, Goldberg's opinions regarding inequitable conduct are unreliable and are therefore stricken.

6. Goldberg May Testify as to Non-Infringement

Medisim argues that Goldberg's refusal to consider 510(k) materials in reaching his non-infringement opinions reflects "a methodology that is arbitrary, unscientific, and unreliable."[104] This claim is without merit because Goldberg did not simply disregard the 510(k) materials. Instead, he explained at length why he considered them to be unreliable descriptions of the Accused Products, and why he believed it was inappropriate for Lipson to rely on them.[105]

Medisim's assertion that BestMed's brief on this point amounts to a "revisionist attempt to show that Goldberg's decision of [sic] the 510(k) documents is sensible" because "there was no Goldberg analysis of the K-Jump 510(k) documents"[106] is similarly incorrect. Goldberg clearly states that he considered the references listed in Exhibit B to his rebuttal report. As that list contains the 510(k)

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103 *See id.* at 207.

104 Medisim Mem. at 22.

105 *See* Goldberg Rebuttal Report at 17-20.

106 Medisim Rep. Mem. at 9.

materials, the charge that Goldberg ignored them is specious. That he declined to discuss them more thoroughly simply indicates that he believed the reasons already noted above to be sufficient. Medisim may disagree with his explanation, but its argument that Goldberg's methods in this area are arbitrary is contrary to fact.

Medisim next argues that Goldberg "stumbles when it comes to applying the Court's claim construction" in his enablement analysis.[107] Primarily, Medisim complains of Goldberg's opinion that oral temperatures are not acceptable estimates of core body temperature.[108] This complaint lacks merit.

Togawa, whom Goldberg expressly cites, clearly states that oral temperatures are "about 0.4 C below simultaneously measured mean pulmonary arterial temperature[s]."[109] Next, Goldberg cites a thermometry-industry standard which states that an estimated measurement that varies from its actual target by 0.4 degrees Celsius or more is considered unacceptable in the field.[110] Put together, these two citations support Goldberg's opinion that "conflating oral equivalent temperature with core body temperature under the assertion that oral equivalent

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[107] Medisim Mem. at 24.

[108] *See* Goldberg Rebuttal Report at 22.

[109] Tatsuo Togawa, *Body Temperature Measurement*, 6 Clin. Phys. Physiol. Meas. 83, 91 (1985).

[110] *See* Medisim Rep. Mem. at 10.

temperature is an approximation of core body temperature is contrary to any understanding in the field."[111] Accordingly, Goldberg's opinion that oral temperatures are not acceptable estimates of core body temperatures is not an *ipse dixit* conclusion, but an application of his expertise to claim terms as construed in the *Markman* Order. For these reasons, his non-infringement opinions are not stricken.

B. BestMed's Motion to Exclude

BestMed seeks to exclude those portions of the Lipson Report that it claims are contrary to this Court's *Markman* Order, based on unreliable science, or contrary to law.[112] BestMed also argues that the portions of the Lipson Report explaining K-Jump's 510(k) submissions should be stricken, as such materials do not need expert explanation.[113] Finally, it seeks to exclude the Keegan Report in its entirety.[114]

1. Lipson May Not Testify that the KD-2201 Meets the Deep Tissue Temperature Limitation of the '668 Patent

BestMed argues that Lipson's opinions on whether the accused

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111 *Id.* at 10 (quoting Goldberg Rebuttal Report at 22).

112 *See* BestMed Mem. at 2.

113 *See id.*

114 *See id.* at 17.

product meets the deep tissue temperature limitation of the '668 Patent should be excluded for three reasons. *First*, it argues that he disregarded the stipulated meaning of that term. *Second*, it argues that Lipson's construction of the term is incorrect. *Third*, it argues that his tests are based on junk science.[115] Even if the first and third arguments are decided in Medisim's favor, Lipson's opinion that the accused product meets the deep tissue temperature limitation of the '668 Patent is excluded for the reasons given below.

BestMed argues that Lipson's conclusion that the KD-2201 – one of the allegedly infringing thermometers – measures deep tissue temperature when used in test mode and allowed to reach thermo-equilibrium is "simply nonsensical."[116] This is so, according to BestMed, because a temperature measured at the skin's surface – even in the way Lipson describes – will never reach the temperature of the blood in the underlying temporal artery due to body tissue insulation and environmental conditions. Because Lipson expressly disagrees with that proposition, BestMed argues that his report is "contrary to the laws of physics and clearly wrong" and therefore "frivolous."[117]

Medisim responds in several ways. *First*, it notes that because the

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115 *See* BestMed. Mem. at 3-6.

116 *Id.* at 4.

117 *Id.* at 5-6.

KD-2201 has an insulating rubber hood, "the equilibrium temperature is not the same as a person's external skin temperature that is in equilibrium with the air temperature."[118] *Second*, it argues that BestMed's own expert "acknowledges that the maximum temperature of a probe in contact with a body site 'represents the deep tissue temperature claimed in the '668 patent.'"[119] *Third*, it argues that K-Jump's 510(k) submissions support Lipson's conclusion.[120]

A review of the scientific literature that underlies this dispute shows that neither Medisim nor BestMed is entirely correct. According to both Sessler and the Yamakage/Namiki team, a conductive thermometer implementing the "zero-heat-flux" method developed by Fox and Solman would indeed measure the temperature under the skin, to a depth of approximately one centimeter.[121] Accordingly, by arguing that there is a method by which it is possible to measure deep tissue temperature at the skin surface, Lipson is not saying anything that is facially impossible.

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[118] Medisim Opp. Mem. at 5.

[119] *Id.* at 6.

[120] *See id.*

[121] Michiaki Yamakage & Akiyoshi Namiki, *Deep Temperature Monitoring Using a Zero-Heat-Flow Method*, 17 J. Anesthesia 108, 111 (2003); Daniel I. Sessler, *Temperature Monitoring and Perioperative Thermoregulation*, 109 Anesthesiology 318, 319 (2008).

However, Lipson's implicit conclusion that it is possible to measure deep tissue temperature by allowing the KD-2201 to reach thermo-equilibrium is nonetheless incorrect.[122] This is so because that device does not make use of the zero-heat-flux method. Sessler, on whom Lipson relies, clearly indicates that implementing that method requires the use of two thermistors and a heating element to achieve the condition in which the temperature measured by the thermistor in contact with the skin is the equivalent of deep tissue temperature.[123] The Yamakage/Namiki team – on whom Goldberg relies to rebut Lipson – concurs.[124] Furthermore, Lipson himself states that the KD-2201 had only one thermistor and never mentions that the device has a heating element.[125] He also fails to show that the KD-2201 is capable of measuring deep tissue temperature at the skin surface in some other way.

Medisim argues that all of the forgoing merely establishes that there is "a factual issue on which experts reach difference [sic] conclusions," and that such

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[122] *See* Medisim Opp. Mem. at 4.

[123] Sessler, *supra* note 119, at 319.

[124] *See* Yamakage & Namiki, *supra* note 119, at 108. As Goldberg plainly relies on this article for the proposition that "the maximum temperature of a probe in contact with a body site 'represents the deep tissue temperature claimed in the '668 patent,'" Medisim's assertion that Goldberg agrees with Lipson is incorrect. *See* Medisim Opp. Mem. at 6.

[125] *See* Lipson Report at 15.

a disagreement does not merit striking Lipson's opinion as unreliable under *Daubert* and Rule 702.[126] Far from being a "logical conclusion"[127] or mere factual dispute, however, Lipson's determination that the KD-2201 measures deep tissue temperature at the skin surface is an unsupported *ipse dixit* conclusion, the acceptance of which is tantamount to an abdication of the court's role as gatekeeper of expert testimony.[128] Accordingly, Lipson may not testify that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent.

2. Lipson May Testify that the KD-2201 Meets the Core Body Temperature Limitation of the '668 Patent

BestMed next argues that Lipson's opinion that the KD-2201 meets the "calculate a core body temperature" limitation of the '668 Patent must be excluded for two reasons: (1) that Lipson's use of that term is inconsistent with the *Markman* Order, and (2) that Lipson's testing methodology was flawed.[129]

a. Lipson Followed the *Markman* Order's Construction of "Calculate" and "Core Body Temperature"

At the *Markman* hearing, Medisim argued that peripheral

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126 *See* Medisim Opp. Mem. at 6.

127 *Id.* at 4.

128 *See Pension Comm. of Univ. of Montreal v. Banc of Am. Sec., LLC*, 691 F. Supp. 2d 448, 481 n.211(S.D.N.Y. 2010) (quoting *Vuitton IV*, 525 F. Supp. 2d at 643).

129 *See* BestMed Mem. at 8.

temperatures were core body temperatures. Lipson now argues that readings of oral temperatures "cluster more tightly around the pulmonary artery temperature than other peripheral temperatures,"and that oral temperatures are consequently viewed in the field as acceptable estimates of core body temperature.[130] Accordingly, he argues that even though an oral temperature is not a core body temperature, measuring an oral temperature necessarily "calculates" – that is, uses a "computation to estimate, approximate, predict or determine" – a core body temperature. Based on this understanding, Lipson then concludes that the KD-2201 calculates a core body temperature.[131]

The parties do not dispute that core body temperature can be "calculated" directly by inserting a catheter with a thermistor into the pulmonary artery. However, the *Markman* Order makes clear that a reliable estimation or approximation of the temperature of blood in the pulmonary artery is also a "calculation" of core body temperature.[132] While BestMed may attack the assertion that measurements of oral temperatures approximate core body temperatures, Lipson did not equate the two. Instead, he applied the *Markman* Order's

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[130] Lipson Report at 8.

[131] *See id*. at 30.

[132] *See Medisim Ltd. v. BestMed LLC*, 10 Civ. 2463, 2011 WL 2693896, at *10 (S.D.N.Y. July 8, 2011).

construction of the terms "calculate" and "core body temperature" to his understanding of the relationship between oral temperatures and core body temperatures. Accordingly, Lipson may testify to his opinion that the KD-2201 calculates a core body temperature.

b. Lipson's Testing Methodology Is Not Flawed

BestMed argues that Lipson misused the KD-192 – an admittedly non-infringing K-Jump thermometer – by drinking hot or cold liquids before using it to take temperatures.[133] The results of that "misuse" show that oral temperatures are noticeably affected by the consumption of such liquids when measured directly by thermometers like the KD-192.[134] By contrast, the temperature taken by the KD-2201 was not affected by the ingestion of hot or cold liquids. Accordingly, Lipson concluded that the KD-2201 displayed something other than direct oral temperature.[135] It was to illustrate this point that Lipson "misused" the KD-192,[136] and taken in that context, there was nothing inappropriate about him doing so.

BestMed also complains that Lipson's conclusion that the KD-2201 corrects from "test mode" readings to "normal mode" readings by use of an

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133 *See* BestMed Mem. at 11.

134 *See* Lipson Report at 20.

135 *See* Medisim Opp. Mem. at 12.

136 *See* Lipson Declaration at ¶ 5.

algorithm is unreliable for two reasons: (1) that the "test mode" reading cannot be a first step in obtaining the "normal mode" reading, because the former takes several minutes, while the latter takes only seconds, and (2) that Lipson completely failed to analyze the underlying source code controlling both modes.[137]

Lipson did not say that the KD-2201 first takes a "test mode" temperature and then uses it to calculate a "normal mode" temperature. Instead, he stated that the "normal mode" temperature is several degrees higher than the "test mode" temperature.[138] Furthermore, there is no doubt that he considered the source code.[139] Accordingly, both of these arguments are unavailing, and do not merit striking this portion of Lipson's report.[140]

3. Lipson's Analysis of 510(k) Materials Is Appropriate

BestMed asserts that Lipson's analysis of K-Jump's 510(k) submissions should be excluded under Rule 702 because "[t]here is no specialized

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[137] *See* BestMed Mem. at 12-13.

[138] *See* Lipson Report at 23.

[139] *See id.* at 18.

[140] BestMed also complains that Lipson's water bath tests are flawed because he equates the temperature of the water bath to deep tissue temperature without any support. *See* BestMed Mem. at 12. This argument is without merit, as Lipson clearly explains his reasoning for doing so; namely, that the water bath was the only source of heat to the thermometers tested, just as deep tissue temperature is the only source of heat for temperatures measured at the skin. *See* Lipson Declaration at ¶ 4.

knowledge necessary to read a 510(k)."[141] Having reviewed the 510(k) materials provided on this motion, I agree with Medisim that such materials are highly technical in nature, and find Lipson's use of such materials in reaching his opinions was appropriate.[142]

4. Lipson's Rebuttal Report Applies the Relevant Law

BestMed argues that portions of Lipson's rebuttal report should be stricken because he ignored the relevant law of enablement.[143] Specifically, BestMed complains that Lipson "neglects to cite any part of the '668 Patent specification," and that the materials he does cite should not be considered in an enablement analysis.[144]

As noted above, the patent specification must teach one skilled in the art how to practice the claimed invention. A corollary to this rule, also noted above, is that the specification need not disclose minor details that would be known to such a person. Lipson acknowledges these rules in his report.[145] Thus, BestMed's real complaint is that Lipson reached a different conclusion than its

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141 *See* BestMed Mem. at 14.

142 *See* Medisim Opp. Mem. at 14.

143 *See* BestMed Mem. at 14.

144 *See id.* at 16.

145 *See* Lipson Rebuttal Report at 12-13.

own expert.

It is equally clear that the materials Lipson considered were appropriate. While it is true that the patent specification is viewed as it stood on the date of filing for purposes of an enablement analysis,[146] an expert need not limit himself to the patent specification to assess the state of the art at that time. Accordingly, the fact that Lipson's complained-of citations were not incorporated into the patent specification by reference at the time of filing is irrelevant.[147] All of those documents pre-date the '668 Patent and were therefore appropriate matter to consider when assessing the state of the art at the time of filing.[148] For all these reasons, Lipson's rebuttal report will not be stricken for failure to apply the relevant law of enablement.

5. The Keegan Report Is Excluded

BestMed claims that the Keegan Report should be excluded under Rules 702 and 403 because it is flawed in two major ways: (1) Keegan used an

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[146] *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).

[147] Specifically, BestMed complains that Lipson cites to three patents issued to Weiss, Gregory, and Seifert. *See* BestMed Mem. at 15.

[148] BestMed also complains that Lipson again mis-uses the terms "deep tissue temperature" and "core body temperature." *See* BestMed Mem. at 16. As his "deep tissue temperature" opinions in his rebuttal report are the same as those in his initial report, they are excluded for the same reasons.

improper respondent universe, and (2) Keegan used an improper control product.[149]

a. Keegan's Respondent Universe Was Improper

When analyzing a claim under the Lanham Act, a court must consider "whether defendant's use of [a mark entitled to protection] is likely to cause consumers confusion as to the origin or sponsorship of the defendant's goods."[150]

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[149] BestMed also claims that Keegan biased the respondent pool by instructing them that "there is often a relationship between a retail store and its source manufacturers." BestMed Mem. at 23. Medisim argues that Keegan merely "correct[ed] for the possibility that some respondents might have been unaware of the potential relationship between the retailer and manufacturer," and that doing so was an appropriate way to "control *against* improper bias." Medisim Opp. Mem. at 24-25 (emphasis in original).

The use of a control group is the gold standard for eliminating survey responses due to a respondent's pre-existing beliefs and other "background noise." Diamond on Survey Research at 399. A carefully crafted instruction may have a similar effect, albeit in a more subjective way. *See id.* at 397. However, where the same instruction is given to both the control group and the test group, its effect will necessarily be negated if the control functions appropriately, which Medisim states is the case here. *See* Medisim Opp. Mem. at 25. Accordingly, I am not convinced that the instruction improperly biased the survey results.

Finally, BestMed complains that Keegan's survey did not reflect actual marketplace conditions. *See* BestMed Mem. at 18. Because the other issues raised by BestMed are dispositive, I decline to reach this issue.

[150] *Virgin Enters.*, 335 F.3d at 146. *Accord Starbucks Corp.*, 588 F.3d at 114 ("To prevail on a trademark infringement and unfair competition claim under [section 32(1) or section 43(a) of the Act], in addition to demonstrating that the plaintiff's mark is protected, the plaintiff must prove that the defendant's use of the allegedly infringing mark would likely cause confusion as to the origin or sponsorship of the defendant's goods with plaintiff's goods."); *Vuitton II*, 454 F.3d at 115. As the Supreme Court has made clear, the same likelihood of confusion analysis applies regardless of the name given to the trademark claim – e.g. false designation of origin, infringement, or something else. *See Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 780 (1992).

There is a likelihood of consumer confusion if "numerous ordinary prudent purchasers are likely to be misled or confused as to the source of the product in question because of the entrance in the marketplace of defendant's mark.'"[151] Accordingly, a survey purporting to determine whether there is a likelihood of consumer confusion at the point of sale must survey potential purchasers.

As noted above, Keegan used screening questions to ensure that survey respondents were likely to shop at stores that sold thermometers made by the parties. However, he did nothing to ensure that his respondents were likely to purchase those products. According to BestMed, this failure means that Keegan surveyed the wrong universe of respondents, leading to results that are necessarily irrelevant to this case.[152]

Medisim argues that "a digital thermometer is not a major planned purchase . . . for which a survey could easily locate individuals who are 'in the

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[151] *Playtex Prods., Inc. v. Georgia-Pacific Corp.*, 390 F.3d 158, 161 (2d Cir. 2004) (quoting *Cadbury Beverages, Inc. v. Cott Corp.*, 73 F.3d 474, 477-78 (2d Cir. 1996)). *Accord Chambers v. Time Warner, Inc.*, 282 F.3d 147, 155 (2d Cir. 2002) ("Where there is a claim of consumer confusion [as] to the association of a product or service with another person's trademark, the central inquiry is whether it is likely that 'an appreciable number of ordinarily prudent purchasers' will be misled as to the source or sponsorship of the product or service in question." (quoting *EMI Catalogue P'ship v. Hill, Holiday, Conors, Cosmopulos, Inc.*, 228 F.3d 56, 61-62 (2d Cir. 2000))).

[152] *See* BestMed Mem. at 22.

market.'"[153] Because of this, Medisim believes that "a survey of those who had already used this type of product and shopped at relevant stores would be good candidates for a potential purchaser."[154] This argument is unavailing for several reasons. *First*, a party may not simply excuse itself from surveying the relevant universe of respondents because it is difficult to assemble an appropriate sample of that population. *Second*, as Keegan himself notes, "repeat purchasing [of digital thermometers] is relatively infrequent . . . ."[155] If one credits this statement and makes the reasonable assumption that digital thermometer users own their devices, the logical conclusion is that such persons are not likely to purchase a digital thermometer within a reasonable timeframe.

Without information as to when current digital thermometer users bought their device, there is no way to tell if their familiarity with digital thermometers is equivalent to that of a true potential purchaser. Keegan intimates that current users obtain sufficient product familiarity by dint of shopping at the stores that sell the relevant products. As BestMed notes, however, shoppers at

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153 Medisim Opp. Mem. at 23.

154 *Id.* at 23-24.

155 12/20/11 Declaration of Warren Keegan Submitted in Connection with Medisim's Opposition to BestMed's Motion to Exclude Certain Expert Reports at 1.

such stores are also exposed to thousands of unrelated products.[156] Amidst this deluge, there is no basis to equate the knowledge of a person admittedly not shopping for a given product with that of a potential purchaser.

Based on the forgoing, I conclude that Keegan failed to survey the proper universe of respondents. As Medisim correctly notes, methodological errors typically go to the evidentiary weight of a survey, rather than its admissibility. Nonetheless, as Professor McCarthy notes, the selection of the respondent universe is a "crucial step," because "even if the proper questions are asked in a proper manner, if the wrong [universe is surveyed], the results are likely to be irrelevant."[157]

b. Keegan's Control Design Was Flawed

BestMed raises two points in support of its argument that Keegan used an improper control: (1) the control product Keegan used "does not exist in the marketplace and shares few similarities with either the K-Jump-manufactured or the outdated Medisim-manufactured thermometers," [158] and (2) that because Keegan did not specify which features of the Medisim product's packaging he was

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156 *See* BestMed Rep. Mem. at 8.

157 6 McCarthy on Trademarks § 32:170 at 32-351.

158 BestMed Mem. at 20. For this reason, BestMed believes that any reported confusion "is clearly due to the differences in the stimuli in the Test and Control conditions." *Id.*

testing, it is impossible to tell what generated the reported confusion, thereby "rendering [Keegan's] analysis meaningless."[159]

While a party may seek protection for the "overall look" of a product under the auspices of the trade dress doctrine, it cannot thereby "dispense with an articulation of the specific elements which comprise its distinct dress."[160] If this were not so, there would be nothing to prevent trade dress law from "slipping into protection for an otherwise unprotectable style, theme, or idea . . . ."[161]

Keegan does not explain what elements of Medisim's packaging constitute a protectable trade dress. Instead, he simply alludes to the fact that BestMed's product "was so similar in design and packaging to the Medisim product that it would cause consumer confusion . . . ."[162] Rather than explaining this omission, Medisim's brief merely indicates that Keegan chose a control that shared "certain characteristics" with the test product.[163] These failures are deeply troubling, and indicative of a serious flaw in the design of Keegan's survey.

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159 *Id.* at 21.

160 *Landscape Forms, Inc. v. Columbia Cascade Co.*, 113 F.3d 373, 381 (2d Cir. 1997).

161 *Gucci America, Inc. v. Guess?, Inc.*, No. 09 Civ. 4373, 2011 WL 5825206, at *6 (S.D.N.Y. Nov. 16, 2011) (quotation marks and citations omitted).

162 Keegan Report at 7.

163 Medisim Opp. Mem. at 22.

Furthermore, I am unable to determine whether Keegan's control was appropriate without understanding the scope of the claimed protection.

d. Because of Its Flaws, the Keegan Report Is Excluded

While both of the flaws noted above are quite serious, neither of them would justify excluding Keegan's report if taken separately. Nonetheless, because each flaw goes to a fundamental element of the survey rather than an issue on the periphery, their combined impact is too significant to overlook under *Daubert* and Rule 702. Accordingly, the Keegan report is excluded in its entirety.[164]

V. CONCLUSION

For the reasons given above, both motions are granted in part and denied in part as follows:

1. Goldberg's inequitable conduct opinions are stricken, along with those portions of his anticipation analysis discussed above;
2. Lipson's opinion that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent is stricken;
3. The Keegan Report is excluded in its entirety.

The Clerk of the Court is directed to close these motions (Docket Nos. 55 and 59).

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[164] Given these substantial flaws, the Keegan report may also be excluded under Rule 403, as any minimal probative value it might retain is substantially outweighed by the risk of unfair prejudice and misleading the jury.

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
March 6, 2012

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